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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,986	06/14/2001	Julian Schroeder	19452A-001210US	9824

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EXAMINER	
BAUM, STUART F	
ART UNIT	**PAPER NUMBER**
1638	11

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,986	SCHROEDER ET AL.	
	Examiner	Art Unit	
	Stuart Baum	1638	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-27 are pending.

Claims 1-27 will be examined on their merits.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5-8, 11-16, 20, and 24-27 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-8, 11-16, 20, and 24-27 are indefinite in the recitation "ABH1". Applicant has not defined the meaning of this term. The name of a nucleic acid coding sequence or protein should give some indication to one skilled in the art, the function of said sequence or protein.

Claims 1, 11, and 20 are indefinite in the recitation "modulates". This is a relative term and does not explicitly state how ABA signal transduction is being altered. How is the signal transduction being affected? Does the over-expression of ABH1 increase or decrease ABA signal transduction in a plant?

Claims 1, 11, and 20 are indefinite in the recitation "at least about". It is not clear what are the limitations of this phrase. Is the sequence at least 70% identical to SEQ ID NO:1 or is the sequence about 70% identical to SEQ ID NO:1?

Claims 1, 11, and 20 are indefinite and confusing because of the use of the word "and" following the word "plant;". As written, the claim is interpreted as comprising two nucleic acid coding sequences, one is a ABH1 polynucleotide and the other is a sequence at least about 70%

identical to SEQ ID NO:1. It is believed that Applicant only wishes to claim one sequence that is at least about 70% identical to SEQ ID NO:1 and is not claiming two sequences. The use Markush language would help clarify this situation. Amending the claim to recite --...ABA signal transduction in a plant selected from the group consisting of: (a).....and (b)...-- will obviate the rejection.

The verb "is" should be deleted from claim 6.

The verb "is" should be deleted from claim 13.

The article "an" should be deleted from the first line of claim 20.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-27 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule comprising any ABH1 polynucleotide from any plant and comprising any sequence exhibiting about 70% sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising at least about 70 % sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising a

polynucleotide that encodes an ABH1 polypeptide exhibiting about 70% sequence identity to SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter, a transgenic plant comprising an above-mentioned sequence, and a method of modulating abscisic acid signal transduction in a plant comprising introducing into a plant an above mentioned sequence.

Applicants isolated their invention from *Arabidopsis* using an activation-tagged screen in which seeds transformed with a construct comprising a 35S promoter were selected by their inability to germinate on medium containing 0.3μM ABA. A resultant family was designated *abh1* and was found to be a recessive, loss-of-function mutant. The ABH1 gene was cloned by plasmid rescue and was found to encode a protein comprising 850 amino acids that exhibited homology to a specific class of human and yeast nuclear RNA cap binding proteins named CBP80, which thus far have not been described in plants. Applicants purport that over-expressing the ABH1 polynucleotide will modulate the abscicis acid signal transduction pathway.

Applicants have not presented data supporting their claims of modulating the signal transduction pathway by over-expressing the sequence in plants. They only over-expression studies provided is complementing the mutant which is not a readily apparent utility, since one skilled in the art would not use the gene for complementing a mutant to get a wild-type plant, since the wild-type plant is already available. Therefore, neither a credible asserted utility or a well established utility has been established for the claimed invention.

Claims 1-27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility

for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. Claims 1-5, 7, 9-12, 14, 16-24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid molecule comprising any ABH1 polynucleotide from any plant and comprising any sequence exhibiting about 70% sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising at least about 70 % sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising a polynucleotide that encodes an ABH1 polypeptide exhibiting about 70% sequence identity to SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter, a transgenic plant comprising an above-mentioned sequence, and a method of modulating abscisic acid signal transduction in a plant comprising introducing into a plant an above mentioned sequence.

Applicants isolated their invention from *Arabidopsis* using an activation-tagged screen in which seeds transformed with a construct comprising a 35S promoter were selected by their inability to germinate on medium containing 0.3μM ABA. A resultant family was designated *abh1* and was found to be a recessive, loss-of-function mutant. The ABH1 gene was cloned by plasmid rescue and was found to encode a protein comprising 850 amino acids that exhibited homology to a specific class of human and yeast nuclear RNA cap binding proteins named CBP80, which thus far have not been described in plants.

The Applicant do not identify structural features unique to the Arabidopsis ABH1 protein, the functional domains of the protein nor the overall function of the protein. The Applicants have not described the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished it from other protein families. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for any ABH1 protein, it remains unclear what features identify an ABH1 protein, including an ABH1 gene or protein with 70% homology to SEQ ID NO:1 or 2. Since an ABH1 protein has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

5. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated nucleic acid molecule comprising any ABH1 polynucleotide from any plant and comprising any sequence exhibiting about 70% sequence

identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising at least about 70 % sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising a polynucleotide that encodes an ABH1 polypeptide exhibiting about 70% sequence identity to SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter, a transgenic plant comprising an above-mentioned sequence, and a method of modulating abscisic acid signal transduction in a plant comprising introducing into a plant an above mentioned sequence.

Applicants isolated their invention from *Arabidopsis* using an activation-tagged screen in which seeds transformed with a construct comprising a 35S promoter were selected by their inability to germinate on medium containing 0.3μM ABA. A resultant family was designated *abh1* and was found to be a recessive, loss-of-function mutant. The ABH1 gene was cloned by plasmid rescue and was found to encode a protein comprising 850 amino acids that exhibited homology to a specific class of human and yeast nuclear RNA cap binding proteins named CBP80, which thus far have not been described in plants.

The Applicants have not reduced to practice their invention, they have only isolated a mutant in *Arabidopsis* with increased sensitivity to ABA. They have not shown genetically or biochemically that their mutant is a complete knockout, nor have they presented any other alleles of their mutant which would further define the function of their cloned invention and they haven't shown that homologues from other plants have the same function. In addition, the Applicants are claiming a method of modulating the abscisic acid signal transduction in plants comprising transforming a plant with a before-mentioned sequence, but Applicants have not presented any data or examples from plants that were transformed with said construct having a modulated abscisic acid signal transduction.

The Applicants are broadly claiming any ABH1 polynucleotide and any sequence that exhibits at least about 70% sequence identity to SEQ ID NO:1 but Applicants have not identified regions of the protein that are conserved and must not be altered, especially in sequences exhibiting at least about 70% sequence identity to SEQ ID NO:1, so as to maintain the proper activity of the protein. Li et al (2000, Science 287 :300-303) teach an ABA-activated serine-threonine protein kinase (AAPK) that has a conserved lysine residue in subdomain II that is critical for adenosine triphosphate binding (page 300, right column, 3rd paragraph). Li et al state "Mutation of this residue yields kinases with reduced or absent catalytic activity".

It cannot be predicted by one of skill in the art that transforming a plant with a component of a signal transduction pathway will lead to predictable results. Transforming plants with the *Arabidopsis Ethylene Response Factor1* (*ERF1*) gene, which is a component of the ethylene signal transduction pathway, will not produce plants exhibiting an ethylene induced phenotype as claimed. Solano et al (1998, Genes and Development 12:3703-3714) teach that over-expressing the *ERF1* gene using the 35S promoter in *Arabidopsis* only produced a partial seedling triple response phenotype. Solano et al state "Expression of only a partial seedling triple response phenotype in these lines is consistent with a role for *ERF1* in mediating a subset of the ethylene responses. ERF1 may act along with other proteins (EREBPs and others) to fully mediate the various seedling responses to ethylene" (page 3708, sentence bridging the left and right columns). This is an analogous situation to the present application because Applicants have stated in the specification that the ABH1 gene encodes a protein exhibiting similarity to CBP80 which is a subunit of a heterodimeric nuclear cap binding complex, together with CBP20 (page

24, lines 22-26). Given that ABH1 requires other components to be active, over-expression of the ABH1 protein will not lead to an increase in activity.

Claims 1, 11, and 20 can be interpreted as meaning a recombinant expression cassette comprising two sequences; an ABH1 polynucleotide and a sequence at least about 70% identical to SEQ ID NO:1 or a sequence that encodes a polypeptide having a sequence at least about 70% identical to SEQ ID NO:2. Given that Applicant is not enabled for one sequence comprising any ABH1 polynucleotide from any plant or an isolated nucleic acid molecule comprising at least about 70 % sequence identity to SEQ ID NO:1 or an isolated nucleic acid molecule comprising a polynucleotide that encodes an ABH1 polypeptide exhibiting about 70% sequence identity to SEQ ID NO:2, Applicant is also not enabled for two sequences, as interpreted from claims 1, 11, and 20.

Due to the unpredictable nature of plant transformation, one of skill in the art can not reasonably generate transformed plants with a desired phenotype using a specific isolated gene. Levels of transgene expression in plants are generally unpredictable and vary between independent transformants; this variability is usually explained by differences in transgene copy number and/or integration site (Finnegan and McElroy, 1994. Bio/technology 12: 883-888 pg. 883 2nd paragraph) Eshed et al (2001, Current Biology 11:1251-1260 pg 1255 2nd paragraph) documented the phenotypes of plants transformed with the 35S CaMV promoter fused to the *KANADI1* gene, which is a gene normally expressed in tissues located on the bottom side of young developing leaves. Of the 30 plants that were transformed with the *KANADI1* gene, 23 plants developed only small narrow cotyledons and an arrested meristem, three produced a few radialized leaves and four appeared normal. These results suggest that transforming plants with

an endogenously expressed gene in regions of the plant in which it is not normally expressed produces highly unexpected and unpredictable results. For one skilled in the art, undue experimentation would be necessary to produce a plant with a desired phenotype while using an undefined enhancer region as a promoter.

Given the unpredictability of modulating a signal transduction pathway by transforming a plant with a component of a signal transduction pathway for the reasons stated above, and given the unpredictability of modulating a signal transduction pathway using a sequence exhibiting at least about 70% sequence identity with SEQ ID NO:1 for the reasons stated above; and given the unpredictability of producing a plant with a desired phenotype by transforming said plant with an endogenous gene that is not normally expressed through-out the plant for the reasons stated above; and given the lack of guidance and examples of selecting a sequence from the multitude of sequences that are encompassed in the broad recitation of the claims that would be active in modulating the ABA signal transduction in a plant; given the state of the art that teaches one component of a multi-component system will only produce a partial response, it would require undue experimentation by one skilled in the art to practice the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al (April 2, 1999, NCBI Accession Number 4558656).

The claims are drawn to an isolated nucleic acid molecule comprising an ABH1 polynucleotide that modulates ABA signal transduction in a plant and encodes an ABH1 polypeptide having a sequence at least about 70% identical to SEQ ID NO:2, further comprising a promoter operably linked to the ABH1 polynucleotide wherein the promoter is tissue-specific and expresses in guard cells.

Lin et al teach a DNA sequence from *Arabidopsis* chromosome II that encodes a cap-binding protein comprising the amino acid sequence set forth in SEQ ID NO:2. It would be an inherent property of the protein to modulate ABA signaling in a plant. The DNA sequence is operably linked to an endogenous promoter that is tissue specific and expresses in guard cells and as such, Lin et al anticipate the claimed invention.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 305-2272.

Stuart Baum Ph.D.

September 25, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600